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May 1, 2025

Via CM/ECF only

Hon. Georgette Castner, U.S.D.J.
United States District Court, District of New Jersey
402 East State Street
Trenton, NJ 08608

Re: *Lovaglio v. Baston*, No. 3:23-cv-21803-GC-RLS

Dear Judge Castner:

Pursuant to the Court's April 17, 2025 Order, below please find 1) a status report concerning the New Jersey Department of Health's (DOH) revised retention policy for the Newborn Screening Program that went into effect November 1, 2024; and 2) the State's supplemental briefing on mootness and on Plaintiffs' standing to pursue the prospective injunctive relief set forth in Paragraph 179 of the First Amended Complaint (FAC).

1. Status. The minor Plaintiffs' bloodspots are currently being preserved only because the parent Plaintiffs previously turned down their destruction. Specifically, in December 2023, shortly after Plaintiffs filed their Complaint, the State offered to destroy the minor Plaintiffs' bloodspots under DOH's then-existing policy, but the parent Plaintiffs "decline[d] to accept NJ's offer." *See* Reilly / Herbert email exchange (attached hereto as Exh. A). Then, on October 31, 2024—the day before DOH's new policy went into effect that slated the minor Plaintiffs' bloodspots for automatic destruction given their age—the State again emailed Plaintiffs seeking clarification of whether their prior preference not to destroy the bloodspots remained in effect. *See* Chung email (attached hereto as Exh. B). Plaintiffs never responded, and in light of the relevance of their particular bloodspots to this pending



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litigation, DOH found it prudent to continue to abide by Plaintiffs' earlier direction not to destroy them. DOH stands ready to destroy the bloodspots under its new policy should Plaintiffs choose to permit it, which would leave Plaintiffs in the same position they would be in if the relief they seek in the FAC were granted.¹

2. Mootness and Standing to Pursue Prospective Injunctive Relief. Under

Supreme Court precedent, Plaintiffs' claims are moot due to a change in the governing framework. For example, in a recent case, New York City amended its rule regarding firearm transportation to allow persons to transport guns to a shooting range or a second home. *See New York State Rifle & Pistol Ass'n v. City of New York*, 590 U.S. 336, 337-38 (2020) (per curiam). Given that the amendment offered "the precise relief that petitioners requested in the prayer for relief in their complaint," the Court held that their "claim for declaratory and injunctive relief with respect to the City's old rule is therefore moot." *Id.* at 338-39; *see also Princeton Univ. v. Schmid*, 455 U.S. 100, 103 (1982) (holding case moot where "University substantially amended its regulations" and challenged policy was "no longer in force") (per curiam); *Diffenderfer v. Cent. Baptist Church of Miami*, 404 U.S. 412, 414-15 (1972) (case moot where "only relief sought" was declaratory and prospective injunctive relief regarding statute subsequently repealed) (per curiam).²

The same principle applies here. In ¶ 179 of their FAC, Plaintiffs ask that the Court, "moving forward," order DOH to either obtain informed consent to retain bloodspots, return

¹ To date, DOH has destroyed 1014 of 1600 boxes (63.38%) of previously retained bloodspots that are older than two years. Destruction of the remainder is ongoing, with DOH under contract with one vendor that hauls the boxes away and another vendor that destroys them as biowaste. As for newer bloodspots, they are being routinely destroyed on a monthly basis as they reach the two-year mark.

² It is unsurprising that Circuit courts, including the Third Circuit, have followed the Supreme Court's lead. *See, e.g., Clark v. Governor of New Jersey*, 53 F.4th 769, 775 (3d Cir. 2022) ("Governor's partial rescission of the orders challenged in the amended complaint ended any live controversy," rendering case "moot"); *Akiachak Native Cnty. v. U.S. Dep't of Interior*, 827 F.3d 100, 113-14 (D.C. Cir. 2016) (noting it is "perfectly uncontroversial and well-settled principle of law" that "when an agency has rescinded and replaced a challenged regulation, litigation over the legality of the original regulation becomes moot"); *Gulf of Maine Fishermen's All. v. Daley*, 292 F.3d 84, 88 (1st Cir. 2002) ("The promulgation of new regulations and amendment of old regulations are among such intervening events as can moot a challenge to the regulation in its original form"); *Khodara Env't, Inc. ex rel. Eagle Env't L.P. v. Beckman*, 237 F.3d 186, 194, 196 (3d Cir. 2001) ("Where a law is amended so as to remove its challenged features," a ruling about the legality of those features, absent claims for damages, "would serve no purpose"); *Am. Rivers v. Nat'l Marine Fisheries Serv.*, 126 F.3d 1118, 1124-25 (9th Cir. 1997) (holding that where federal agency issued one Biological

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the bloodspots, *or* destroy them. Under its new policy, DOH is implementing the third option Plaintiffs pursued, *i.e.*, destroying all bloodspots older than two years unless it has the parents' express permission to retain them.³ That part of the case is therefore moot.

And Plaintiffs cannot save their case from mootness by refusing to permit the destruction of bloodspots that would otherwise be destroyed by operation of the new policy. This situation is substantially similar to the facts in *F.V. v. Cherry Hill Township Board of Education*, No. 1:21-CV-18096-KMW-SAK, 2023 WL 2662697 (D.N.J. Mar. 28, 2023), where plaintiffs sought services from a school district for their disabled minor daughter B.V. The school board did not "ever resist providing B.V. with make-up sessions. To the contrary, the Board had actively attempted on several occasions to make up sessions, but were inexplicably rebuffed at every turn by Plaintiffs and their counsel." *Id.* at *11. This court found that, given plaintiffs' "illogical refusal of services that are readily available for the taking," the case was moot. *Ibid.*; see also *Campbell-Ewald Co. v. Gomez*, 577 U.S. 153, 185 n.1 (2016) (Alito, J., dissenting) ("A plaintiff cannot thwart mootness by refusing complete relief presented on a silver platter.");⁴ *Jarrett v. United States*, 79 F.4th 675, 676, 680 (6th Cir. 2023) (tax refund case dismissed as moot where IRS "issu[ed] a full refund check" but taxpayer "refused to cash it"; court found "no reason that mootness should turn on what a taxpayer does with a check"). Here, as in *F.V.*, Plaintiffs are refusing complete relief simply to keep this case alive. DOH would have destroyed minor Plaintiffs' bloodspots in the ordinary course (which would have mooted this case), but only refrained from doing so because of the parties' prior communications.

As for DOH's retention of bloodspots up to the two-year mark, Plaintiffs lack standing to challenge this provision of the new policy. Again, a Supreme Court case is directly on point. In *Hall v. Beals*, 396 U.S. 45 (1969) (per curiam), Appellants objected to Colorado's six-month residency requirement to vote. *Id.* at 47. Colorado amended its statute to require only a two-month residency, which meant that Appellants "could have voted in the 1968 presidential election." *Id.* at 48. The Court concluded that the case was moot because it had "lost its character as a present, live controversy." *Id.* Appellants "cannot alter the fact that so far as they are concerned nothing in the Colorado legislative scheme as now written adversely

Opinion that plaintiffs challenged, but then agency issued a superseding Biological Opinion, claims regarding older opinion were moot); see also *Hinton v. District of Columbia*, 567 F. Supp. 3d 30, 42-45 (D.D.C. 2021) (holding that challenges to "superseded" housing policy were rendered moot by enactment of amended housing policy).

³ DOH is retaining for ten years one de-identified bloodspot from all positive samples.

⁴ *Campbell-Ewald*'s holding that "an unaccepted settlement offer or offer of judgment does not moot a plaintiff's case" where the plaintiff has sued for damages, 577 U.S. at 157-58, 165, is inapposite here because Plaintiffs have not sued for damages. Instead, they have sued for declaratory and injunctive relief. FAC ¶¶ 1, 177-80.

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affects ... their present interests.” *Id.* Appellants then sought to enjoin enforcement of the two-month requirement, but the Court rejected that as well, holding: “Nor does the result differ because the appellants denominated their suit a class action on behalf of disenfranchised voters. The appellants cannot represent a class of which they are not a part.” *Id.* at 48-49 (cleaned up). The same holds true here: Plaintiffs’ challenge on behalf of their own children (who are all older than two years old) is moot under the new policy’s default provision of destruction at two years, and Plaintiffs lack standing to seek declaratory and injunctive relief on behalf of children under two years of age.

No exception to mootness applies. Preliminarily, the voluntary cessation exception to mootness is inapplicable. Where, as here, “the plaintiff seeks only injunctive relief, voluntary cessation of the challenged conduct” will still moot the action if “it is ‘absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.’” *Lackey v. Stinnie*, 604 U.S. ___, 145 S. Ct. 659, 669 (2025) (quoting *Buckhannon Bd. & Care Home, Inc. v. W. Va. Dep’t of Health and Hum. Resources*, 532 U.S. 598, 609 (2001)). Here, numerous factors militate against a reasonable expectation of recurrence. First, nearly two-thirds of the previously retained bloodspots have already been destroyed and destruction of the remainder is ongoing. DOH cannot retain what no longer exists. Second, there are considerable sunk costs. DOH spent time and money reprinting the kits to explain the new retention policy, putting information up on the website, and educating hospitals about the change. Third, due to historical reasons, DOH’s old bloodspot retention policy was tethered to a broader records retention policy that required a long retention period.⁵ As part of its rollout of the new policy, DOH received the State Records Committee’s approval to de-couple those retention processes and has now set a shorter retention period specifically for the bloodspots.

Individually and cumulatively, these structural obstacles to reversion render unreasonable any expectation that DOH will re-establish its 23-year retention policy. *See Sutton v. Rasheed*, 323 F.3d 236, 249 (3d Cir. 2003) (claims for declaratory and injunctive relief were moot when prison enacted a “new [] policy” that provided the relief sought, and there were “strong administrative incentives making it unlikely that the new policy will be reversed”). The State has thus met its “heavy burden of persuading the court” that the voluntary cessation exception to mootness does not apply because “the challenged conduct

⁵ Back over 60 years ago at the inception of the newborn screening program, the bloodspots were collected on filter paper that was physically attached to the carbon copy of the test requisition form (known as the IEM1) that contained all of the newborn’s demographic information. The carbon copies of the IEM1s (and hence the attached bloodspots) were considered records that needed to be retained. *See* previous records retention schedule at page 2, item 0003-0000 (attached hereto as Exh. C).

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cannot reasonably be expected to start up again.” *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000) (quotation omitted).

Further, the capable-of-repetition-yet-evading-review exception to mootness does not apply here either. This exception requires “a reasonable expectation or a demonstrated probability that the *same* controversy will recur involving the *same* complaining party.” *Gulden v. Exxon Mobil Corp.*, 119 F.4th 299, 309 (3d Cir. 2024) (quoting *FEC v. Wis. Right to Life, Inc.*, 551 U.S. 449, 463 (2007)); *see also City of Los Angeles v. Lyons*, 461 U.S. 95, 109 (1983) (“capable-of-repetition doctrine applies only in exceptional situations, and generally only where the named plaintiff can make a reasonable showing that he will again be subjected to the alleged illegality”). Here, the minor Plaintiffs cannot possibly make such a showing regarding the bloodspots that were collected when they were newborns, and the parent Plaintiffs have not met their burden of demonstrating a probability that they will have future children whose bloodspots DOH will retain against their will. *See* FAC ¶¶ 55, 68 (parent Plaintiffs pleading that they are “considering whether to have more children in New Jersey”). Indeed, even if they did have more children, the new policy allows parents to request destruction of their child’s bloodspots as soon as initial testing is complete, obviating any potential injury to these hypothetical future children. Moreover, even if the parent Plaintiffs were deemed to have met their burden under the “capable-of-repetition” prong, their argument would still falter on the “evading review prong.” To satisfy this prong of the exception, ““the challenged action must be in its duration too short to be fully litigated prior to its cessation or expiration.”” *Gulden*, 119 F.4th at 309 (quoting *Weinstein v. Bradford*, 423 U.S. 147, 149 (1975) (per curiam)). Here, absent a request for destruction or extended retention, DOH retains for two years bloodspots that test negative. This period is more than the 600 days that the Third Circuit found sufficient to defeat an evading review argument. *See id.* at 309-10.

In short, “[n]o matter how vehemently the parties continue to dispute the lawfulness of the conduct that precipitated the lawsuit, the case is moot if the dispute is no longer embedded in any actual controversy about the plaintiffs’ particular legal rights.” *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013). “If an intervening circumstance deprives the plaintiff of a personal stake in the outcome of the lawsuit, at any point during litigation, the action can no longer proceed and must be dismissed as moot.” *Genesis Healthcare Corp. v. Symczyk*, 569 U.S. 66, 72 (2013). Here, DOH’s amended policy offers these Plaintiffs all the relief they seek, and they lack any injury-in-fact to seek prospective injunctive relief.

CONCLUSION

For these reasons, and those briefed in the State’s pending motion to dismiss, the Court should dismiss the FAC.

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Respectfully submitted,

MATTHEW J. PLATKIN
ATTORNEY GENERAL OF NEW JERSEY

By: /s/ Jean P. Reilly
Jean P. Reilly
Assistant Attorney General

And

Amy Chung
Deputy Attorney General

c: All counsel of record (via CM/ECF)

EXHIBIT A



[EXTERNAL] RE: Newborn Blood Destruction Form

From Christie Hebert <chebert@ij.org>

Date Tue 12/19/2023 1:05 PM

To Jean Reilly <Jean.Reilly@law.njoag.gov>; Robert Frommer <rfrommer@ij.org>; Brian Morris <bmorris@ij.org>

Cc Marvin Freeman <Marvin.Freeman@law.njoag.gov>; Amy Chung <Amy.Chung@law.njoag.gov>; CJ Griffin <CGriffin@pashmanstein.com>

Thank you for sharing the form, Jean.

We conferred with our clients. Plaintiffs decline to accept NJ's offer to use the form to request the destruction of their sons' blood samples at this time.

We look forward to speaking with you again in January.

From: Jean Reilly <Jean.Reilly@law.njoag.gov>

Sent: Thursday, December 14, 2023 11:25 AM

To: Robert Frommer <rfrommer@ij.org>; Brian Morris <bmorris@ij.org>; Christie Hebert <chebert@ij.org>

Cc: Marvin Freeman <Marvin.Freeman@law.njoag.gov>; Amy Chung <Amy.Chung@law.njoag.gov>; CJ Griffin <CGriffin@pashmanstein.com>

Subject: Newborn Blood Destruction Form

Hi Folks: Nice speaking with all of you this morning. Attached as promised is New Jersey's form that allows parents to request destruction of their kid's newborn blood sample. Here is the link as well:

<https://www.nj.gov/health/phel/public-health-lab-testing/newborn-screening-lab/> As discussed, if the Plaintiff-parents want to request destruction of their children's newborn blood spot, you can send the completed forms to me and I'll see to it that the lab works on them quickly. Other folks requesting destruction should submit the form directly to the New Jersey Department of Health Newborn Screening Lab. Thanks, Jean

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EXHIBIT B



Lovaglio v. Baston

From Amy Chung <Amy.Chung@law.njoag.gov>

Date Thu 10/31/2024 2:37 PM

To Brian Morris <bmorris@jj.org>; Jean Reilly <Jean.Reilly@law.njoag.gov>; Michael Zuckerman <Michael.Zuckerman@njoag.gov>

Cc Viviana Hanley <Viviana.Hanley@njoag.gov>; Elizabeth Tingley <Elizabeth.Tingley@law.njoag.gov>; Michael Sarno <Michael.Sarno@law.njoag.gov>; Marvin Freeman <Marvin.Freeman@law.njoag.gov>; Christie Hebert <chebert@jj.org>; CJ Griffin <CGriffin@pashmanstein.com>; Robert Frommer <rfrommer@jj.org>; Cara Di Silvio <cdisilvio@jj.org>; Monica Banta <mbanta@pashmanstein.com>; Melina Meneguin <Melina.Meneguin@njoag.gov>; Nathaniel Levy <Nathaniel.Levy@njoag.gov>

Brian – as you know, DOH’s process for destroying NBS samples older than two years is beginning tomorrow (Nov. 1). We understand from your prior communications that plaintiffs want the samples associated with them/their children to be affirmatively retained for purposes of this litigation, so in reliance on that understanding, those samples will not be destroyed by default at the two-year mark. Please let us know if that understanding is inaccurate, so that DOH can do whatever plaintiffs prefer. Until we hear back, we will continue to operate on the understanding that plaintiffs want DOH to continue retaining those specific samples.

Amy Chung

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EXHIBIT C

Records Retention and Disposition Schedule		Agency: S460412		Schedule: 005		Page #:1 of 4				
Department:	Health-Public Health and Environmental Laboratories-Inborn Errors of Metabolism (IEM) Program	Agency Representative:								
		Title:								
		Phone #:								
SCHEDULE APPROVAL: Unless in litigation, the records covered by this schedule, upon expiration of their retention periods, will be deemed to have no continuing value to the State of New Jersey and will be disposed of as indicated in accordance with the law and regulations of the State Records Committee. This schedule will become effective on the date approved by the State Records Committee.										
Status		Last Updated Date/Time		Approved Date			Effective Date			
Published		10/13/2015 9:10 AM								
Record Series #	Record Title and Description				Retention Policy		Disposition	Citation		
					Total Retention Period	Minimum Period in Agency				
		Audit	Alternate Media	Archival Review	Vital Record	Confidential				
0001-0000	IEM Patient History (IEM-10/IEM-20/IEM-21) --- Contains history files which include reports to hospitals and physicians on all patients with abnormal results. Also contains recommendations for treatment. Note: for retention time requirements see N.J.S.A. 26:8-5 et seq.									
0001-0001	IEM Patient History (Original)				10 yrs after most recent discharge or age 23 whichever is longer	10 yrs after most recent discharge or age 23 whichever is longer	Destroy			
0001-0002	IEM Patient History - Normals and Abnormals (Electronic)				10 yrs after most recent discharge or age 23 whichever is longer	10 yrs after most recent discharge or age 23 whichever is longer	Erase/Degauss			

Records Retention and Disposition Schedule		Agency: S460412			Schedule: 005			Page #:2 of 4		
Record Series #	Record Title and Description	Audit	Alternate Media	Archival Review	Vital Record	Confidential	Retention Policy		Disposition	Citation
							Total Retention Period	Minimum Period in Agency		
0002-0000	Laboratory Test Results Report --- Contains results of specimen tests which are generated either manually or by computer, and sent to hospitals or physicians. Note: for retention time requirements see N.J.S.A 26:8-5 et seq.									
0002-0001	Laboratory Test Results Report (Original)						10 yrs after most recent discharge or age 23 whichever is longer	10 yrs after most recent discharge or age 23 whichever is longer	Destroy	
0002-0002	Laboratory Test Results Report (Electronic)						10 yrs after most recent discharge or age 23 whichever is longer	10 yrs after most recent discharge or age 23 whichever is longer	Erase/Degauss	
0003-0000	Newborn Screening Request (IEM-1/IEM-1a) --- Contains all pertinent patient information to perform screening assay (analysis) and determine any abnormal results. Used for demographic information pertinent to screening assay interpretation and patient identification. Note: for retention time requirements see N.J.S.A 26:8-5 et seq.						10 yrs after most recent discharge or age 23 whichever is longer	10 yrs after most recent discharge or age 23 whichever is longer	Destroy	
0004-0000	Program Statistical Information --- Contains historical information on the IEM program. This information is used to determine frequency and distribution of ethnic and/or high risk groups within the state with regard to metabolic disorders. Note: for retention time requirements see N.J.S.A. 26:8-5 et seq.		X	P			10 yrs after most recent discharge or age 23 whichever is longer	10 yrs after most recent discharge or age 23 whichever is longer	Archival Review	

Records Retention and Disposition Schedule		Agency: S460412				Schedule: 005		Page #:3 of 4		
Record Series #	Record Title and Description	Audit	Alternate Media	Archival Review	Vital Record	Confidential	Retention Policy		Disposition	Citation
							Total Retention Period	Minimum Period in Agency		
0005-0000	Quality Control Test Records (IEM Form Numbers 5, 8, 12, 13, 25, 36, 38, 39, 40, 43, 44, 45, 46, 48, 50, 53) --- Contains quality control tests which prove the acceptable limits of tests performed on patient specimens and assay (analysis) acceptability. Demonstrates that results on patient specimens are valid. Provides information on equipment maintenance and instrument calibration. Note: for retention time requirements see N.J.S.A. 26:8-5 et seq.						10 yrs after most recent discharge or age 23 whichever is longer	10 yrs after most recent discharge or age 23 whichever is longer	Destroy	
0006-0000	Result Code History File --- Contains a record of appropriate results coding for the purpose of interpreting the significance of test results. This constitutes a historical record of result codes as they evolved through the years, and are necessary to properly interpret results on older test reports. Used as a reference for historical test interpretation. Note: for retention time requirements see N.J.S.A. 26:8-5 et seq.						10 yrs after most recent discharge or age 23 whichever is longer	10 yrs after most recent discharge or age 23 whichever is longer	Destroy	
0007-0000	Sickle Cell Test Isoelectrofocusing (IEF) Gels --- Isoelectrofocusing (IEF) gels containing patient specimens with hemoglobin bands. Used as a reference for unidentified bands reported as abnormal and identified abnormal hemoglobin bands. Note: for retention time requirements see N.J.S.A. 26:8-5 et seq.						10 yrs after most recent discharge or age 23 whichever is longer	10 yrs after most recent discharge or age 23 whichever is longer	Destroy	
0008-0000	Specimens for IEM Testing (IEM-3) --- Contains a summary list which is prepared by the submitting hospital or physician and accompanies a group of specimens when submitted. Used as an aid in locating a particular patient specimen, and assuring that all specimens are received. Also used as a cross reference to the patient specimen number. Note: for retention time requirements see N.J.S.A. 26:8-5 et seq.						10 yrs after most discharge or age 23 whichever is longer	10 yrs after most discharge or age 23 whichever is longer	Destroy	

Records Retention and Disposition Schedule		Agency: S460412			Schedule: 005		Page #:4 of 4			
Record Series #	Record Title and Description	Audit	Alternate Media	Archival Review	Vital Record	Confidential	Retention Policy		Disposition	Citation
							Total Retention Period	Minimum Period in Agency		
0009-0000	Worksheet from Laboratory Tests (IEM Form Numbers 9, 17, 26, 29, 30, 32, 42, 49, 51) --- Contains results of all metabolic assays on all patients. Used as a source of assay results for each patient specimen. Worksheet may be generated manually or as a computer printout. Note: for retention time requirements see N.J.S.A. 26.8-5 et seq.						10 yrs after most recent discharge or age 23 whichever is longer	10 yrs after most recent discharge or age 23 whichever is longer	Destroy	
0010-0000	Analytical Results									
0010-0001	High Performance Liquid Chromatograph (HPLC) Raw Data Report for Serum Phenylalanine and Tyrosine Analysis --- Analyses performed on individuals who tested positive at birth for PKU. Report shows the levels of phenylalanine, and tyrosine, and chromatograms for each analysis.						23 Years	2 Years	Destroy	
0010-0002	Request for Serum Phenylalanine and Tyrosine Analysis (CHEM-27) --- Request for ongoing testing of individuals diagnosed at birth with Phenylketonuria (PKU).						23 Years	2 Years	Destroy	
0010-0003	Serum Phenylalanine Laboratory Report --- Report of analyses performed on individuals who tested positive at birth for PKU. Report shows the level of phenylalanine, and chromatograms for each analysis.						23 Years	2 Years	Destroy	